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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,518	07/09/1999	JOHN C. REED	P-LJ-3578	8259

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/350,518

Applicant(s)

REED, JOHN C.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 16, 20-27, 32-34, 36, 37, 44 and 50-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed June 13, 2003 is acknowledged. Claims 11, 13, 14, 20, 21, 26, 32, 36, 37, 44, 50-53, 55-61 were amended. Claims 62-66 were added.

Claims 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-66 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejection Withdrawn:

3. The rejection of claims 11-14, 20, 21, 26, 32, 33, 36, 37, 44, 50-53, and 55-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Rejections Maintained and New Grounds of Rejection:

4. The rejection of claims 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-61 under 35 U.S.C. 112, first paragraph, is maintained and made for new claims 62-66. New grounds of rejection are presented.

Applicant's arguments have been carefully considered but are unpersuasive.

The rejection is maintained on the grounds that the specification fails to enable methods where BAG-1 protein levels are measured in a body fluid. Although the specification clearly contemplates measurements in body fluids, the specification provides no teachings to demonstrate that the data obtained for tissues that demonstrates a correlation of BAG-1 protein levels and distant metastasis free survival or overall survival will be mirrored in measurements that are to be done in body fluids. Although it is possible to measure BAG-1 in body fluids, this is not the grounds for rejecting the claims. The issue is whether the data that will be obtained will correlate with a disease outcome. This does not appear to be readily predictable. For example, because BAG-1 is normally found in the nucleus, and the abnormality is that BAG-1 is expressed in the cytosol, how will one be able to know from a body fluid measurement whether one is measuring nuclear BAG-1 or cytosolic BAG-1. Thus, the rejection of the claims with respect to the issue of measurements in body fluids is maintained for the reasons of record.

New grounds of rejection are also presented. With respect to measurements in body fluids, and also tissue samples, all of the claimed methods lack support that is commensurate in scope with the scope of the claims, because the claimed methods read on methods where a reference level is determined or an amount of BAG-1 protein is determined. Methods comprising the determination of a reference level or a reference amount of BAG-1 protein are not enabled by the specification because the specification fails to provide any examples of appropriate reference levels by providing an actual measurement of an amount of BAG-1 protein above which it is judged that one has determined a "high" level of BAG-1 protein.

Thus, the specification merely provides an invitation to experiment to discover appropriate reference levels or reference amounts, or reference tissues or in vitro cell lines. The

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specification provides one example of determining whether patients have a “high” level or a “low” level, but the determination is done by determining a cut-off H-score for immunohistochemical staining of a tissue sample. The H-score is determined by analyzing staining intensity and percentage of cells that stain positive for BAG-1. The specification fails to demonstrate how it was determined that an H-score of greater-than-or-equal-to (\geq) 150 is the appropriate cutoff. Therefore it cannot be determined if H-scores \geq 150 will apply to any study of breast tumor tissue samples, or if a new cut-off needs to be determined. Additionally, the specification provides no correlation with the cut-off H-score and reference amounts. This is especially a problem for the claimed inventions that read on measurement performed on body fluids, in which the BAG-1 measurements will be measured quantitatively, and not immunohistochemically.

Additionally, the claims are rejected to the extent the claimed inventions are drawn to methods for the prognosis of disease-free survival or overall survival of an individual having breast cancer. The specification fails to provide any methods for the prognosis of disease-free survival of an individual already having a disease, that of breast cancer. Instead, the specification teaches methods for the prognosis of distant metastasis free survival of an individual who will be treated for breast cancer.

5. Claims 11-14, 16, 20-27, 32-34, 36, 37, 44, and 50-66 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are indefinite because each of the independent claims contains the recitation "high" level or "low" level of BAG-1. This renders the claims indefinite because the specification fails to define "high" level or "low" level and none of the claims recite a reference level above which or below which a level may be considered "high" or "low".

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 15, 2003

